BARCODE NO.: D349947; **PRODUCT NAME:** Integrity Powered By Kixor Herbicide (BAS 781 02 H) ; **FILE SYMBOL / REG. NO.:** 7969-ETO (279)

DATE: 30 / SEP / 2009

FEE

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF TGAI/MP [ ] EP [X]**
DP BARCODE No.: D349947 **REG. No.:** 7969-ETO
PRODUCT NAME: BAS 781 02 H
COMPANY: BASF Corporation, Agricultural Products, P. O. Box 13528, Research Triangle Park, NC 27709-3528, USA.

PCC: 118203; **Decision No.:** 389168; **ACTION CODE:** R010.0
FOOD USE [X]
INTEGRATED FORMULATION: Yes [X] No [ ]

PMRA SUBMISSION NUMBER: 2008-0432
PMRA PRODUCT NAME: BAS 781 H EC

FROM: Shyam B. Mathur,
Product Chemistry Team Leader
Technical Review Branch/RD (7505P)

S Bmathur 9/30/09

TO: Kathryn Montague / Joanne Miller, RM 23
Herbicide Branch / RD (7505P)

Formulating Plant's Name and Address:	1. BASF Corporation, 14385 West Port Arthur Road, Beaumont, TX 77705, USA 2. Van Diest Supply Company, 1434 220th Street, Webster City, IA 50595, USA 3. BASF Corporation, Hannibal Plant, 3150 Highway JJ, Palmyra, MO 63461, USA 4. Omnium Winfield Solutions, LLC 280 Imperial Road Hampton, Iowa 50441 (Not listed on the CSF of US EPA)
TGAIs in EP:	BAS 800 H (Saflufenacil TGAI/MUP) Dimethenamid-P Technical Herbicide
Guarantee:	Saflufenacil: 6.24% (NC), 5.93% (LCL), 6.55% (UCL) Dimethenamid-P: 55.04% (NC), 53.39% (LCL), 56.69% (UCL)
MRID Numbers:	471285-01 through 471283-05
Uses:	Food use

INTRODUCTION:

The registrant BASF Corporation has submitted an application package for the registration of a new end use product "BAS 781 02 H". The proposed product is intended for use as a selective pre-emergence herbicide for controlling most annual grasses, broadleaf weeds, and sedges in field corn, sweet corn, popcorn, and grain sorghum. It also provides burndown control of many broadleaf weeds. The proposed product combines two active ingredients: saflufenacil, a potent inhibitor of protoporphyrinogen-oxidase (PPO), and dimethenamid-P (EPA Reg. No. 7969-

155), a chloroacetamide, a root-and-shoot inhibitor that controls susceptible weed seedlings before or soon after they emerge from the soil. The proposed product is an emulsifiable concentrate (EC) formulation containing an aromatic solvent. The product chemistry corresponding to 830 series group A & group B have been submitted under MRID Numbers 471285-01 to 471285-05. The registrant has also submitted a Confidential Statement of Formula (CSF) for basic formulation dated 21st December, 2007 and the product label. The source of the active ingredient saflufenacil (BAS 800H, 97.4%, File Symbol No. 7969-ETL) is under going process of registration with the Agency.

SUMMARY OF FINDINGS:

1. The proposed end use product contains BAS 800H [File Symbol No. 7969-ETL, containing 97.4% saflufenacil] and Dimethenamid-P (s-Dimethenamid) [Reg. No. 7969-155, 97.2%] as the active ingredients with product label claims of 6.24% and 55.04% respectively. The application on the registration for the source of the active ingredient Saflufenacil is under going evaluation process with the Agency.

2. The proposed CSF of basic formulation (dated 12-21-07) is filled out correctly but not completely. The nominal concentrations of the active ingredients concur with the product label claim nominal concentrations. The CSF for basic formulation is in compliance with PR Notice 91-2. All the food use inert ingredients present in the formulation are approved by the Agency and have tolerance exemption for food use (IIAB, 02-06-08). The certified limits for the AI and the food use inert ingredients (except one) are in compliance with standard certified limit table set forth in 40CFR§158.350(b)(2). For one of the food use inert ingredients (present as solvent/diluents), the applicant has proposed extended certified limits and has provided proper justifications. The data submitted corresponding to guidelines 830.1550 (product identity & composition) and 830.1750 (certified limits) do not satisfy the product chemistry data requirements of 40CFR§158.320 & 158.350 respectively. The name of the carry over toxic impurity from the source of AI technical is not included in the CSF. The registrant must calculate (in the EP), the amount of this carry over impurity based on the amount present in the technical AI[MRID No. 471285-01].

3. The data submitted corresponding to guideline 830.1600 (description of materials used to produce the product), 830.1650 (description of formulation process), and 830.1670 (discussion on the formation of impurity) satisfy the data requirements of 40CFR §158.325, §158.335, & §158.340 respectively. The registrant must provide additional information on the formulation process conditions (like temperature, pressure etc.) [MRID No. 471285-01].

4. The data submitted corresponding to guideline 830.1800 (enforcement analytical method) satisfy the data requirements of 40CFR§158.355. A validated RP HPLC-UV method # AFR0068 / 01 have been used for the determination of the BAS 800H content in the proposed end use product. The analyte was determined by reverse phase HPLC utilizing a Varian Polaris C 18-A column, 50 mm x 2.0 mm, 3 µm. The column temperature was 50°C with injection volume of 2 µl. The method utilized a gradient of two mobile phases [water with 0.1% trifluoroacetic acid (TFA) and acetonitrile (ACN) with 0.1% TFA] with a flow rate of 0.5 ml/min. The UV detector was operating at 254 nm. The quantification was performed by internal standard (propyl paraben) calibration using peak area. The second active ingredient dimethenamid–P was determined by validated RPHPLC-UV Method No. AFR0069/01. The analyte was determined by reversed phase chiral HPLC on a Regis (S, S) Whelk-O 1 chiral column (250 x 4.6 mm, 5 µm). The column temperature was 30°C with injection volume of 5 µl. The mobile phase was made of acetonitrile (ACN), isopropyl alcohol (IPA), and water with a flow rate of 1.0 ml/min. The UV detector was operating at 254 nm. The quantification was performed by internal standard (propyl paraben dissolved in IPA) calibration using peak area [MRID No. 471285-01 & -02].

5. The data submitted corresponding to guideline 830 series subgroup B (physical-chemical properties) satisfy the data requirements of 40CFR158.190, excluding one year storage stability (830.6317) and corrosion characteristics (830.6320) data [MRID No. 471285-03, -04, & -05].

6. The registrant has submitted the results of accelerated storage stability study carried out at 25°C & 40°C for nine months and at 50°C for 6 weeks with the test substance which was stored in commercial containers. The results of

these studies indicated that the test substance was stable under these parameters. The registrant has also indicated the long term study corresponding to the guidelines 830.6317(one year storage stability) and 830.620 (corrosion characteristics) is in progress. It is advised that the registrant conduct the one year studies for these guidelines and it is recommended that observations must be made at 0, 3, 6, 9, and 12 month interval periods. The results of one year studies must be submitted to the Agency on completion [MRID No. 471285-05].

CONCLUSIONS:

The TRB has reviewed the product chemistry data submitted for the proposed end use product and has concluded that:

1. The product chemistry data submitted for the guidelines 830 Series Subgroup A & Subgroup B are acceptable, except for one year storage stability & corrosion characteristics studies.
PMRA: Agree.

2. The proposed CSF for basic formulation (dated 12-21-07) is not acceptable for the following reasons:

   - ☐ The name of the carry-over toxic impurity from the source of active ingredient BAS 800H is not listed in the proposed CSF. The proposed basic CSF should be revised to include the name and the amounts of the carryover toxic impurity from the technical source of the active ingredient (7969-ETL). PMRA does not require this addition to its spec form.

   Note: The revised basic CSF (dated 07-30-09) was submitted by the registrant as recommended by the Agency. The revised basic CSF (dated 07-30-09) was found to be acceptable (see PCR dated 08-12-09; DP367791; Reg. No. 7969-279).

   - ☐ According the records of the Agency, the nominal concentration of the active ingredient Dimethenamid-P in the product with Reg. No. 7969-155 is 92.9% and not 97.2% as has been listed on the proposed CSF of the proposed end use product. During the conversation with the applicant (Mr. Craig D. Klepp on April 24, 2008), it was determined, that the registrant has submitted recently (March 2008) an application to amend the CSF by increasing the nominal concentration of Dimethenamid-P (active S-isomer; R-isomer is not active) from 92.9% to 97.4% supported by the 5-batch analysis. This application has not yet reviewed by the Agency. As a result, the approval of the basic CSF for the proposed product BAS 781 02H is contingent upon the evaluation and approval of the proposed CSF for the product with Reg. No. 7969-155.

PMRA: This change in guarantee has recently been proposed to PMRA (Sub. 2009-1435) but until it is registered, the existing approved guarantee of 92.9% for the dimethenamid-P TGAI will be used in Canada.

US EPA: Label claim of 97.2% approved on July 21, 2008

3. The registrant must submit the results of one year storage stability (830.6317) and corrosion characteristics (830.6320) studies on completion.

PMRA: Agree.

4. The registration of the proposed end use product "BAS 781 02 H Herbicide" with File Symbol No. 7969-ETO is contingent to the registration of the active ingredient (BAS 800H) technical source product (File Symbol No. 7969-ETL) which is undergoing process of registration with the Agency.

Good Laboratory Practices Compliance Statement:

The studies contained within this report were conducted in accordance with the Good Laboratory Practice Standards as specified in 40 CFR 160 or equivalent.

yes [X] no [ ] not stated / applicable [ ]

PMRA: The short-term storage stability study was not GLP-compliant.

Label Review

1. The active ingredient statement (chemical identity, nominal concentration) is consistent with the CSF / SPSF.

   yes [X] no [ ]

2. The formulation contains one of the following:

10% or more of a petroleum distillate:	yes [ ]	no [X]
1% or more of methyl alcohol:	yes [ ]	no [X]
sodium nitrite at any level:	yes [ ]	no [X]
a toxic List 1 inert at any level:	yes [ ]	no [X]
arsenic in any form:	yes [ ]	no [X]

3. If yes to any of the above, does the inert ingredients statement (Product label) contain a footnote indicating this?

   yes [ ] no [ ] not applicable [X]

   PMRA: The label statement regarding toxicity to aquatic invertebrates resulting from the presence of aromatic petroleum distillates is being addressed by the Environmental Assessment Directorate.

4. The appropriate physical and chemical hazards statement regarding flammability or explosive characteristics of the product are given on the label:

   yes [ ] no [ ] not applicable [X]

5. The storage and disposal instructions for the pesticide and container are in compliance with PMRA Registration Handbook / PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses:

   yes [X] no [ ] see DACO 8.4 in EAD review summary [ ]

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Chemical and Physical Properties: See Table 1.

Reference: See in column # 3 of the Table #1

Table 1. Chemical & Physical Properties

DACO # / GLN	Title	MRID / Report #	Status[1]	Result[2] or Deficiency
3.5.1 / 830.6302	Colour	R. Yacoub 471285-03 BASF DocID 2007/7013453	A	Clear brown
3.5.2 / 830.6303	Physical State	" " "	A	Liquid
3.5.3 / 830.6304	Odour		N/A	
3.5.4	Formulation Type		A	Emulsifiable concentrate (EC)
3.5.5	Container Material and Description		A	HDPE containers lined with an inner barrier (e.g. polyamide) and with a foil seal
3.5.6 / 830.7300	Density or Specific Gravity	R. Yacoub 471285-03 BASF DocID 2007/7013453	A	Relative density = 1.092 at 20°C
3.5.7 / 830.7000	pH	" " "	A	4. 195 @ 25°C (for 1% solution)
3.5.8 / 830.6314	Oxidizing or Reducing Action	R. Yacoub 471285-04 BASF DocID 2007/7013454	A	Test substance is considered a mild reducing agent. Storing or mixing it with strong oxidizers should be avoided. It does not react with water or with reducing agents (iron filings) and is non-hazardous when in contact with monoammonium phosphate (fire-extinguishing agent).
3.5.9 / 830.7100	Viscosity	R. Yacoub 471285-03 BASF DocID 2007/7013453	A	54.91 mPa.s at 20°C 19.56 mPa.s at 40°C
3.5.10 / 830.6317	Storage Stability Data	R. Yacoub 471285-05 BASF DocID 2007/7013520	U	One year study required. The test substance was found to be stable at 25°C & 40°C for nine months and at 50°C for 6 weeks in commercial container. Two-year study in progress, expected to be complete in 2010.
3.5.11 / 830.6315	Flammability	R. Yacoub 471285-03 BASF DocID 2007/7013453	A	No flash point up to 235°F
3.5.12 / 830.6316	Explodability	" " "	A	No exotherm was detected by DSC when heated up to 400°C at 1.1 MPa (150 psi) pressure.

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Table 1. Chemical & Physical Properties				
DACO # / GLN	Title	MRID / Report #	Status[1]	Result[2] or Deficiency
3.5.13 / 830.6319	Miscibility		N/A	
3.5.14 / 830.6320	Corrosion Characteristics	R. Yacoub 471285-05 BASF DocID 2007/7013520	U	One year study required on commercial containers. To be conducted along with storage stability (830.6317) study.
3.5.15 / 830.6321	Dielectric Breakdown Voltage		N/A	
[1] A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not applicable; U = Upgradeable. [2] For example, "brown" for 830.6302; "1.021" for 830.7300.				

Data Submitted: See Table 2.

Table 2. Data Submitted for the Sharpen Herbicide EP				
DACO # / GLN	Title	MRID / Report #	Status[1]	Details and/or Deficiency[2]
3.2.1 / 830.1600	Description of Starting Material	T. Aldridge 471285-01 BASF DocID 2007/7013645	A	All the suppliers' names and addresses for all the starting materials along with MSDSs have been submitted.
3.2.2 / 830.1620 830.1650	Production / Formulation Process	" " "	A	[redacted]
3.3.2 / 830.1550	Discussion of Impurities	" " "	A	The carry over impurities associated with the active and the inert ingredients are expected to be present in the formulated product. No impurities are expected to be formed during the formulation process and the migration from the packaging material.
3.3.2 / 830.1550	Control Product Specification Form / Confidential Statement of Formula	12-21-07 (Basic CSF) 07-30-09 (revised basic CSF)	U A	The proposed basic U.S. CSF should be revised in order to include the carry over toxic impurity [redacted] from the technical source of the AI. Its amount with upper limit should be indicated on the CSF.
3.3.1 / 830.1750	Certification of Limits	" " "	A	The proposed certified limits for the AI and the inert ingredients are in compliance with the standard certified limit table set forth in 40CFR§158.350(b)(2), except for the solvent for which wider certified limits have been proposed with justification.

Table 2. Data Submitted for the Sharpen Herbicide EP

DACO # / GLN	Title	MRID / Report #	Status[1]	Details and/or Deficiency[2]
830.17	Preliminary Analysis		N/A	*For EP containing non-registered TGAI or for EP which is an ISP only.*
3.4.1 / 830.1800	Enforcement Analytical Method	T. Aldridge 471285-01 BASF DocID 2007/7013645 K. Polowy 471285-02 BASF DocID 2007/7006972	A	The BASF method # AFR0068/01 was used for the AI BAS 800H. The method involves the RPHPLC-UV (254 nm) with internal standard calibration. The method was proved to be linear, accurate and precise for the tested substances. The content of the AI DMTA-P was determined by BASF method No. AFR0069 /01, which uses reversed-phase chiral HPLC-UV (254 nm) with internal standard calibration. Propyl paraben was used as an internal standard in both analytical methods. The method was validated for precision, linearity and accuracy.

[1] A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not applicable; U = Upgradeable

[2] Refer to CBI Appendix A for details

ATTACHMENT: CONFIDENTIAL APPENDIX

Manufacturing process information may be entitled to confidential treatment

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CONFIDENTIAL APPENDIX A: MANUFACTURING, COMPOSITION AND FORMULANT INFORMATION.

[redacted]

[redacted]

Conclusion: The data provided for the guidelines 830.1600, 830.1620, and 830.1670 have been discussed sufficiently and no additional data are required.

3.3.1 / 830/1750 Certification of Limits

The nominal concentration (NC) of the active ingredients and the lower and upper certified limits (LCL & UCL) are shown in Table 1.

Table 1. Certification of Limits

Active Ingredient	NC (w %)	LCL (w %)	UCL (w %)
Saflufenacil (BAS 800 H)	6.24	5.93	6.55
Dimethenamid-P (s-Dimethenamid)	55.04	53.39	56.69

Conclusion: No additional data required.

1. The calculated NC, based on the pure active ingredient (PAI), is identical to that on the label.

   yes [X] no [ ]

2. The certified limits are within the standard limits as per DACO 3.3.1/40CFR§158.350 or are adequately explained if different.

   yes [X] no [ ] not applicable [ ]

3.4.1 / 830.1800 Enforcement Analytical Method

Reference: T. K. Aldridge, "BAS 781 02H (68 g/L BAS 800H + 600 g/L Dimethenamid-P EC). Group A-Product Identity, Composition and Analysis", BASF DocID Number: 2007 / 7013645; MRID No. 471285-01.

Reference Validation of method: K. Polowy, "Validation of Analytical Method AFR0068 / 01 and AFR0069/01, and GLP Certification of BAS 781 01H Formulation Lot 1632-15, BAS 781 UN H Formulation Lot 1632-35-7, and BAS 781 UO H Formulation Lot 1632-38", BASF DocID Number: 2007 / 7006972; MRID No. 471285-02.

The following table presents the details of the method used. Note that, in the applicant's documents, the formulation corresponding to that being reviewed here is identified as BAS 781 UO H Solution.

Table 2. Details of the analytical method used to determine Saflufenacil (BAS 800H) and Dimethenamid-P in BAS 781 02H

Method ID	Method # AFR0068 / 01	Method # AFR0069/01
Sample preparation	AFR0068/01 & AFR0069/01: Typically, into a 1-oz bottle, weigh approximately 100 mg of sample. Add 2 mL of Internal Standard Stock Solution and 23 mL Sample Diluent. Sonicate if necessary to dissolve (typically 5 minutes). Mix well. Filter through a 0.45 µm PTFE syringe filter discarding the first few mLs to waste. Transfer a small amount to a HPLC vial for injection. Samples should be prepared in duplicate and each solution should be injected at least twice. Sample diluent: 75% ACN : 25% water	
Instrument	Agilent 1100 series HPLC a quaternary pump, variable wavelength detector or diode array detector, automated liquid sampler, column oven and a solvent degasser. Agilent LC ChemStation Software and Target Chromatographic Analysis Software	
Detector	UV-VIS detector operating at 254 nm for both methods	
Column	Varian Polaris C18-A column (50 x 2.0 mm, 3 µm particle size)	Regis (S,S) Whelk-O 1 chiral column (250 x 4.6 mm, 5 µm particle size)

Table 2. Details of the analytical method used to determine Saflufenacil (BAS 800H) and Dimethenamid-P in BAS 781 02H

Mobile phase (for LC)	Composition A: water with 0.1% Trifluoroacetic acid (TFA) Composition B: Acetonitrile (ACN) with 0.1% TFA Gradient: Mobile Phase: Time (Minute) / Comp A / Comp B 0 / 80 / 20 7 / 43 / 57 8 / 30 / 70 9 / 80 / 20 12 / 80 / 20	Gradient: Mobile Phase: Time (min) / ACN / IPA / Water 0 / 15 / 35 / 50 15 / 15 / 35 / 50 16 / 40 / 35 / 25 17 / 15 / 35 / 50 24 / 15 / 35 / 50 IPA = Isopropanol
Oven temperature	50°C	30°C
Quantitation	Quantitation was performed by internal standard (IS, propyl paraben) calibration using peak area.	
Retention time	Propyl paraben (IS): approximately 4.0 minutes; BAS 800H: approximately 6.1 minutes.	Propyl paraben (IS): approximately 6.1 minutes; Dimethenamid-P: approximately 9.3 minutes.
Total run time	Not provided	
Chromatograms	Representative chromatograms submitted for blanks, calibration standards and samples, showing no interference with the peaks of interest.	

The validation data are shown in Table 3.

Table 3. Validation data for Saflufenacil & Dimethenamid-P in BAS 781 02H

Method ID	Method type	Linearity	Recovery (%)	RSD (%)	Method
AFR0068/01	RP HPLC-UV	Range 0.04-0.59 mg/ml	101.9	0.19	Acceptable
AFR0069/01	Chiral RP HPLC-UV	Range 0.80-2.99 mg/ml	99.9	0.13	Acceptable

Conclusion: Analytical methods provided for the determination of the active ingredients were assessed to be selective, precise and accurate for use as enforcement analytical methods.

3.3 Specifications:

Reference: T. K. Aldridge, "BAS 781 02H (68 g/L BAS 800H + 600 g/L Dimethenamid-P EC). Group A- Product Identity, Composition and Analysis", BASF DocID Number: 2007 / 7013645; MRID No. 471285-01.

3.3.2 / 830.1550 Control Product Specification Form / Confidential Statement of Formula

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Acceptable Revised basic CSF (dated 07-30-09)

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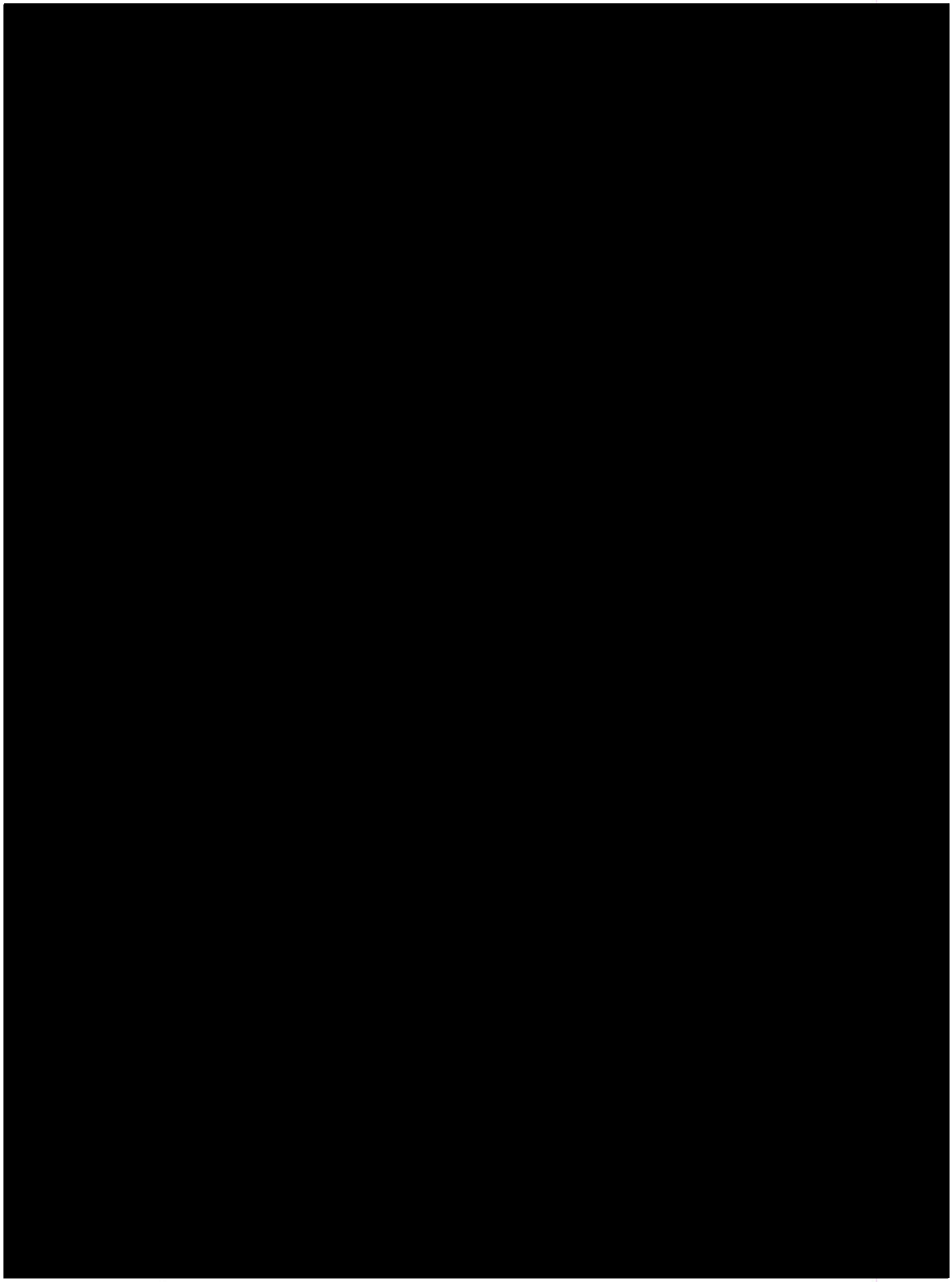
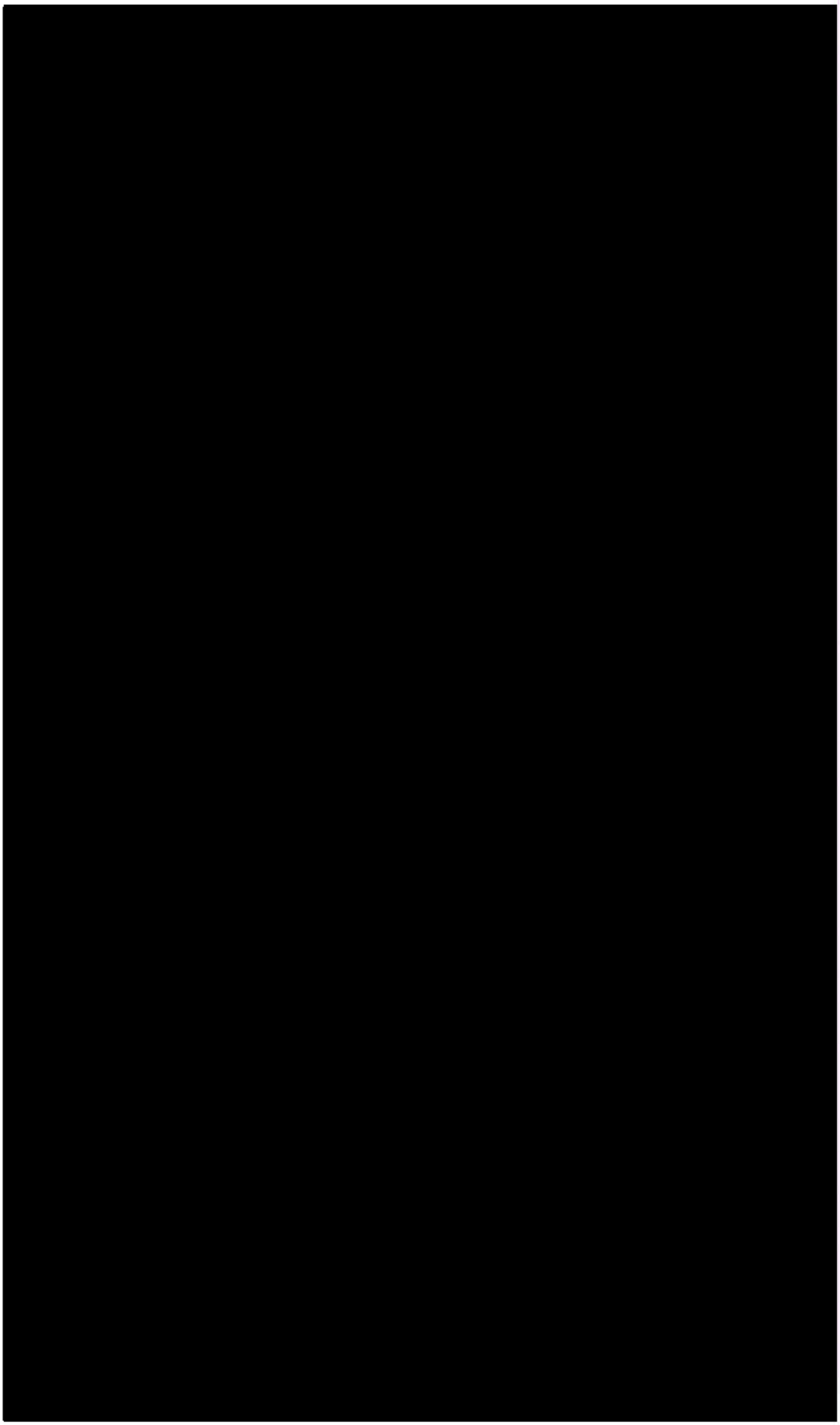
Rejected Basic CSF (dated 12-21-07)

[redacted]

Because the registered guarantee of the dimethenamid-P TGAI is slightly different in Canada, the resulting EP specifications are different as well and have been copied as follows:





Manufacturing process information may be entitled to confidential treatment

3.4.2 Impurities of human health or environmental concern

Chemical name: [redacted]

Level detected: [redacted]

Has the manufacturer used the **best available technology** to reduce the amount of impurities to the lowest level?

yes [ ] no [X] not stated / applicable [ ]

Pages 17-18 - *Confidential Statements of Formula may be entitled to confidential treatment*